FDA bases its estimates of the number of respondents and total annual responses on the submissions that the Agency has received in the past 3 years for each product type. To calculate the estimate for the hours per response values, we assumed that the information requested is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission. We believe that this effort should take no longer than 15 minutes (0.25 hour) per response. FDA estimates that it will receive 1 submission from 10 shell egg producers annually, for a total of 10 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 2.5 hours, rounded to 3. FDA estimates that it will receive 1 submission from 120 dairy product producers annually, for a total of 120 annual responses. Each submission is estimated to take 0.25 hour per response for a total of 30 hours. FDA estimates that it will receive one submission from five game meat and game meat product producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive one submission from five animal casings producers annually, for a total of five annual responses. Each submission is estimated to take 0.25 hour per response for a total of 1.25 hours, rounded to 1 hour. FDA estimates that it will receive one submission from three gelatin producers annually, for a total of three annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. FDA estimates that it will receive one submission from three collagen producers annually, for a total of three annual responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour. Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: November 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29483 Filed 11–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for reports of corrections and removal.

DATES: Submit either electronic or written comments on the collection of information by January 24, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, e-mail: *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control Number 0910–0359)—Extension

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Administration Modernization Act (FDAMA) of 1997 (21 U.S.C. 301) (Pub. L. 105–115). Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, within 10 working days of initiating such correction or removal. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
806.10	666	1	666	10	6,660

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
806.20	90	1	90	10	900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are manufacturers and importers of medical devices. FDA reviewed reports of device corrections and removals submitted to the Agency for the previous 3 years as part of responding to the current request for approval of the information collection requirements for §§ 806.10 and 806.20. This information was obtained through the Agency's voluntary recall provisions (*i.e.*, 21 CFR part 7). The specific information requested was the total number of class I, II, and III recalls for the last 3 years. This information was obtained from the Agency's Recall Enterprise System—a database of all recalls submitted to the Agency.

This information is relevant since a § 806.10 report is required for all class I and II recalls. Although class III recalls are not required to be submitted to FDA (by § 806.10) a record must be kept in the firm's § 806.20 file. Therefore, the number of class I and II recalls can be used to estimate the maximum number of reports that are required to be submitted under § 806.10. Also, the recordkeeping burden can be estimated based upon the number of class III recalls, which are not required to be reported but must be retained in a § 806.20 file.

FDA has determined that estimates of the reporting burden for § 806.10 should be revised to reflect a projected 7.3 percent increase (from the last PRA numbers) in reports submitted to FDA as class I and II. FDA also estimates the recordkeeping burden in § 806.20 should be revised to reflect a reduction of 6.8 percent (from the last PRA numbers) in records filed and maintained under this section. The estimates of time needed to collect part 806 information have not changed.

Dated: November 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29520 Filed 11–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Application Requirements for the Low Income Home Energy Assistance Program (LIHEAP) Model Plan.

OMB No.: 0970–0075.

Description: States, including the District of Columbia, Tribes, Tribal Organizations and Territories applying for LIHEAP block grant funds must submit an annual application (Model Plan) that meets the LIHEAP statutory and regulatory requirements prior to receiving Federal funds. A detailed application must be submitted every three years. Abbreviated applications may be submitted in alternate years. There have been no changes in the Model Plan since the approval of the addition of the LIHEAP Program Integrity Assessment Supplement by the Office of Management and Budget earlier this year.

Respondents: State, Local or Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Program Integrity Assessment and Plan	216	1	1	216
Detailed Model Plan	72	1	1	72
Abbreviated Model Plan	144	1	.33	47.5
Estimated Total Annual Burden Hours				335.5